UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/068,299	02/06/2002	Fiona M. Wood	AVT-001	8540

42532 7590 07/09/2010

PROSKAUER ROSE LLP
ONE INTERNATIONAL PLACE
BOSTON, MA 02110

EXAMINER	
BARNHART, LORA ELIZABETH	
ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
07/09/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/068,299	WOOD ET AL.	
	Examiner	Art Unit	
	Lora E. Barnhart	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 April 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29,34-63,65 and 67-79* is/are pending in the application.

4a) Of the above claim(s) *34-60,62 and 67-74* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29,61,63,65 and 75-79* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/29/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendments

Applicant's amendments filed 4/29/10 to claims 29, 61, 65, 75, 76, 78, and 79 have been entered. No claims have been canceled or added in this reply. Claims 29, 34-63, 65, and 67-79 remain pending in the current application, of which claims 29, 61, 63, 65, and 75-79 are being considered on their merits. Claims 34-60, 62, and 67-74 remain withdrawn from consideration at this time. References not included with this Office action can be found in a prior action. Any rejections of record not particularly addressed below are withdrawn in light of the claim amendments and applicant's comments.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 29, 61, 63, and 75-79 are rejected under 35 U.S.C. 102(b) as being anticipated by Baur et al. (1997, WO 08/23602; reference N).

Baur teaches a cell suspension comprising melanocytes, keratinocytes, and fibroblasts in a serum-free medium. See page 23, lines 19-21; and page 15, lines 19-21. Baur's suspension is produced by obtaining skin tissue from human donors during surgery and floating the tissue in 0.5% trypsin "for a sufficient time to effect cell separation," for example at 37°C for about 30-60 minutes. See page 8, lines 11-31.

Baur characterizes the cells as “dissociated” and “separated," indicating that the suspension is a single-cell suspension. See page 8, line 30, and page 15, line 20. The cell ratios in Baur’s suspension are “comparable” to those in the skin tissue sample in the respect that it is possible to compare them to each other. The cells in Baur’s suspension are necessarily autologous to the patients from which the samples were taken.

The claims are product-by-process claims. Product-by-process claims are not necessarily limited by the steps in the claims. See M.P.E.P. § 2113. Accordingly, the only material requirement limiting the compositions in claim 29 and 61 is that they contain keratinocyte basal cells, melanocytes, and fibroblasts in a suspension lacking cellular congregates (e.g., a single-cell suspension) and further lacking xenogenic serum. The choice of starting material, isolation steps, choice of enzyme, and amount of enzyme do not affect the properties of the composition, absent evidence to the contrary. Baur’s composition contains all of the positively recited elements of applicants’ claims and lacks the necessarily excluded elements.

Claim 65 is rejected under 35 U.S.C. 102(b) as being anticipated by Baur et al. (1997, WO 08/23602) taken in light of Hart (2002, U.S. Patent 6.432,666; reference A).

The teachings of Baur are relied upon as above. Although Baur is silent as to the presence of Langerhans cells in the suspensions, Hart teaches that trypsinized skin suspensions contain Langerhans cells. See Example 1 at column 5. Therefore, Langerhans cells are inherently a component of Baur’s suspension.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 29, 61, 63, 65, and 75-79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baur et al. (1997, WO 08/23602) taken in view of Lucas et al. (1994, U.S. Patent 5,328,695; reference B) and Hart (2002, U.S. Patent 6.432,666).

Baur teaches a cell suspension comprising melanocytes, keratinocytes, and fibroblasts in a serum-free medium. See page 23, lines 19-21; and page 15, lines 19-21. Baur's suspension is produced by obtaining skin tissue from human donors during surgery and floating the tissue in 0.5% trypsin “for a sufficient time to effect cell separation,” for example at 37^{o}C for about 30-60 minutes. See page 8, lines 11-31. The cell ratios in Baur’s suspension are “comparable” to those in the skin tissue sample

in the respect that it is possible to compare them to each other. The cells in Baur's suspension are necessarily autologous to the patients from which the samples were taken.

Baur does not explicitly teach that large cell aggregates are absent from the suspension. Regarding claim 65, Baur does not explicitly teach that the suspension includes Langerhans cells.

Lucas teaches filtering cell suspensions, including skin suspensions, through 20μm filters to remove aggregates prior to culturing. See column 11, lines 20-28.

Hart teaches that trypsinized skin suspensions contain Langerhans cells. See Example 1 at column 5.

A person of ordinary skill in the art would have had a reasonable expectation of success in passing Hart's suspension through Lucas's filter because Lucas teaches that cells may pass through the filter and remain viable. The decision to remove aggregates would have constituted routine optimization, given that Lucas teaches that filtering aggregates out of cell suspensions before culturing the cells was known at the time of the invention.

The person of ordinary skill in the art would have had a further reasonable expectation of success that the suspension of Baur contains Langerhans cells because Hart teaches that trypsinization of skin, the process Baur used, yields a cell suspension that contains Langerhans cells. See M.P.E.P. § 2141.02, section V.

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was made to remove any large aggregates from Baur's suspension,

which Hart teaches includes Langerhans cells, using Lucas's filter prior to culturing Baur's cells because Lucas teaches and exemplifies doing so prior to culturing.

Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill at the time the invention was made.

Response to Arguments

Applicants' arguments in the 4/29/10 reply regarding the art rejections of record and the declaration made by inventor Fiona M. Wood under 37 C.F.R. 1.132 ("the Wood declaration") have been fully considered as they pertain to the new grounds of rejection, but they are not persuasive of error. The examiner believes that applicants' concerns have been fully addressed by the new Baur reference. The claim amendments require for the first time that the composition contain a population comprising keratinocyte basal cells, melanocytes, and fibroblasts; previously, all that was required was that the cells be viable. The new rejections were necessitated by the amendments to the independent claims.

Applicants allege that the term "comparable" should be interpreted as "similar." See reply, page 12, end of first paragraph. However, the term "comparable" is not explicitly provided with such a limiting definition, and in any case, the degree of "similarity" is not limited in the claims or the specification. The constituents in the suspension of Baur are necessarily comparable to some degree with the tissue that gave rise to that suspension. There is no evidence that the selection of dissociation method has a material effect on the properties of the claimed composition, e.g. that one manner of dissociation destroys or enriches a given cell type to such a degree that the

composition of suspension is not reasonably similar to the composition of the skin sample.

The examiner notes that in the working examples, applicants employ 0.5% trypsin at 37°C for 5-45 minutes to dissociate the skin sample, and Baur teaches incubating skin in 0.5% trypsin at 37°C for 30-60 minutes. Compare page 20, lines 17-19, of the instant specification with page 8, line 30, of Baur. Baur and the instant specification concur that the choice of incubation time may vary. See page 20, lines 19-22, of the instant specification with Baur's suggestion to incubate "for a sufficient time to effect cell separation." The examiner further notes that the working examples carry out steps that are encompassed by the steps recited in claims 29 and 61, but the examples contain no evidence that the suspension has any particular number of any particular cell type. If the ratio of cells within the suspension is critical, evidence to that effect (preferably, evidence comparing applicants' suspension to Baur's) would be probative.

Applicants' concerns at pages 14-19 about the presence of all of the cell types recited in the claims and the absence of congregates within the prior art suspensions are fully addressed in the above rejections.

No claims are allowed. No claims are free of the art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E. Barnhart whose telephone number is (571)272-1928. The examiner can normally be reached on Monday-Thursday, 9:00am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lora E Barnhart/
Primary Examiner, Art Unit 1651